MEMORANDUM

Date: December 15, 2005

From: Director, Regulations and Policy Staff (HFM-17), CBER

To: Jennie Butler, Division of Dockets Management (HFA-305)

Subject: Docket No. 1980N-0208, Biological Products; Bacterial Vaccines and

Toxoids; Implementation of Efficacy Review; Final Rule and Final Order

Please add the enclosed reference documents to Docket No. 1980N-0208, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Final Rule and Final Order. An index for the documents is also enclosed. Thank you.

Karnleen Swisher